DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3628. Adulteration of phenobarbital tablets. U. S. v. 4 Bottles, etc. (F. D. C. No. 31399. Sample Nos. 25563–L, 25565–L.)

LIBEL FILED: July 27, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 25, 1951, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: *Phenobarbital tablets.* 4 25,000-tablet bottles, 12 1,000-tablet bottles, and 20 5,000-tablet bottles of green tablets, and 1 drum of 280,000 tablets, and 15 1,000-tablet bottles, 8 5,000-tablet bottles, and 3 25,000-tablet bottles of white tablets at Philadelphia, Pa.

RESULTS OF INVESTIGATION: The interstate shipment of the tablets was made in bulk containers. After receipt of the shipment, a portion of the tablets was repackaged into bottles and relabeled by the consignee.

Analysis showed that the green tablets contained not more than 62 percent of the labeled amount of phenobarbital, whereas the United States Pharmacopeia provides that phenobarbital tablets contain not less than 94 percent of the labeled amount of phenobarbital. Further analysis showed that the white tablets failed to meet the test specified in the United States Pharmacopeia regarding permissible variation in the weight of individual tablets and the time required by the tablets to disintegrate in water.

LABEL, IN PART: (Bottle) "Phenobarbital ½ Grain * * * Green [or "White"]."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the strength (green tablets) differed from, and the quality (white tablets) fell below, the standard set forth in the compendium. The tablets were adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: November 29, 1951. Default decree of condemnation and destruction.

3629. Adulteration and misbranding of Estrotron (estrogenic hormone). U. S. v. 9 Dozen bottles * * *. (F. D. C. No. 31208. Sample No. 28281–L.)

LIBEL FILED: June 21, 1951, Northern District of California.

ALLEGED SHIPMENT: On or about July 6 and 31, 1950 by the Pitman-Moore Co., Div. of Allied Laboratories, Inc., from Indianapolis, Ind.

PRODUCT: 9 dozen bottles of *Estrotron* at Sacramento, Calif. Examination showed that the product contained not more than 1.64 milligrams of estrogenic ketosteroids per cubic centimeter.

LABEL, IN PART: (Bottle and carton) "10 cc. Size * * * Estrotron 2 mg. (20,000 I. U.) per cc. in Peanut Oil A highly purified estrus producing extract from the urine of pregnant mares, consisting primarily of estrone with smaller quantities of naturally occurring estrogens, dissolved in Peanut Oil and standardized to 20,000 I. U. of activity per cc."

*See also No. 3621.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the product contained less than the declared amount of estrogenic ketosteroids per cubic centimeter: (Bottle and carton label) "* * * Estrotron 2 mg. (20,000 I. U.) per cc. * * * consisting primarily of estrone with smaller quantities of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc. * * *" and (accompanying leaflet entitled "Estrotron") "* * * containing 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc."

DISPOSITION: October 29, 1951. The shipper having appeared as claimant and admitted that the product was below potency, judgment of condemnation was entered and the court ordered that the product be released under bond to be reprocessed in compliance with the law, under the supervision of the Food and Drug Administration.

3630. Adulteration of uterine capsules. U. S. v. 69 Cartons * * *. (F. D. C. No. 31523. Sample No. 21901-L.)

LIBEL FILED: On or about September 14, 1951, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about April 30, 1951, by Globe Laboratories, from Fort Worth, Tex.

PRODUCT: 69 cartons of *uterine capsules* at New Orleans, La. Examination showed that the product contained no sodium perborate.

LABEL, IN PART: "Globe Uterine Capsules 1 Dozen * * * Active Ingredients 100%: Sodium Perborate 39%, Boric Acid 60%, Iodoform 1%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess, namely, "Sodium Perborate 39%."

DISPOSITION: October 11, 1951. Default decree of condemnation and destruction.

3631. Adulteration and misbranding of uterine capsules. U. S. v. 23 Cartons, etc. (F. D. C. No. 31904. Sample Nos. 20846-L, 20847-L.)

LIBEL FILED: October 17, 1951, Northern District of Alabama.

ALLEGED SHIPMENT: On or about April 3, May 9, and June 11, 1951, by the Globe Laboratories, from Fort Worth, Tex.

PRODUCT: *Uterine capsules.* 23 cartons, each containing 3 capsules, and 13 cartons, each containing 12 capsules, at Birmingham, Ala. Analysis showed that the product contained approximately 10 percent of the declared amount of sodium perborate.

LABEL, IN PART: "Globe Uterine Capsules Active Ingredients 100%: Sodium Perborate 39%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 39 percent sodium perborate.

Misbranding, Section 502 (a), the label statement "Sodium Perborate 39%" was false and misleading as applied to this article, which contained less than 39 percent sodium perborate.

DISPOSITION: November 21, 1951. Default decree of condemnation and destruction.